

DOCKET NO.: TIBO-0029

PATENT



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re Application of:
Brendan Larder, Stuart Bloor, Kurt
Hertogs, Pascale Alfons Rosa Dehertogh
and Rudy Jean Marc Mortier
Application No.: 09/836,477

Confirmation No.: 8810

Group Art Unit: 1631

Filing Date: April 18, 2001

Examiner: Lori A. Clow

For: METHODS FOR MEASURING THERAPY RESISTANCE

DATE OF DEPOSIT: July 14, 2006

I HEREBY CERTIFY THAT THIS PAPER IS BEING
DEPOSITED WITH THE UNITED STATES POSTAL
SERVICE AS FIRST CLASS MAIL, POSTAGE PREPAID,
ON THE DATE INDICATED ABOVE AND IS
ADDRESSED TO THE UNITED STATES PATENT AND
TRADEMARK OFFICE, P.O. BOX 1450, ALEXANDRIA,
VA 22313-1450.

TYPED NAME: Andrew T. Serafini
REGISTRATION NO.: 41,303

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Pursuant to 37 CFR § 1.56 and in accordance with 37 CFR §§ 1.97-1.98, information relating to the above-identified application is hereby disclosed. Inclusion of information in this statement is not to be construed as an admission that this information is material as that term is defined in 37 CFR § 1.56(b).

☐ In accordance with § 1.97(b), since this Information Disclosure Statement is being filed either within three months of the filing date of the above-identified application, within three months of the date of entry into the national stage of

the above identified application as set forth in § 1.491, before the mailing date of a first Office Action on the merits of the above-identified application, or before the mailing date of a first Office Action after the filing of request for continued examination under § 1.114, no additional fee is required.

- ☒ In accordance with § 1.97(c), this Information Disclosure Statement is being filed after the period set forth in § 1.97(b) above but before the mailing date of either a Final Action under § 1.116 or a Notice of Allowance under § 1.311, or before an action that otherwise closes prosecution in the application, therefore:

☐ Certification in Accordance with § 1.97(e) is attached; or

☒ Please charge the deposit account number 23-3050 in the amount of **\$180.00** as set forth in § 1.17(p).

- ☐ In accordance with § 1.97(d), this Information Disclosure Statement is being filed after the mailing date of either a Final Action under § 1.113 or a Notice of Allowance under § 1.311 but before, or simultaneously with, the payment of the Issue Fee, therefore included are: Certification in Accordance with § 1.97(e); and the submission fee of **\$180.00** as set forth in § 1.17(p).

- ☒ Copies of reference numbers 1-35 and 40-49 listed on the attached Form PTO-1449 are enclosed herewith.

- ☒ Copies of reference numbers 36 - 39 on the attached Form PTO 1449 are not required to be submitted pursuant to 37 CFR § 1.98(a)(2)(i).

☐ Copies of references - are not being submitted because they were previously cited by or submitted to the U.S. Patent and Trademark Office in patent application number , filed for

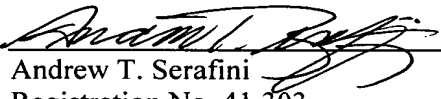
which a claim for priority under 35 U.S.C. § 120 has been made in the instant application.

☐ The relevance of those listed references which are not in the English language is as follows:

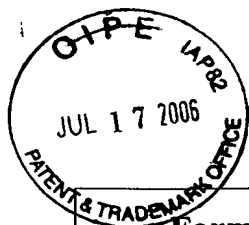
There are no listed references which are not in the English language.

Please charge any deficiency or credit any overpayment to Deposit Account No. 23-3050. This form is submitted in duplicate.

Date: July 14, 2006


Andrew T. Serafini
Registration No. 41,303

WOODCOCK WASHBURN LLP
One Liberty Place - 46th Floor
Philadelphia, PA 19103
Telephone: (215) 568-3100
Facsimile: (215) 568-3439



Form PTO-1449 Modified

List of Patent and Publications
Cited by Applicant
(Use several sheets if necessary)

U.S. Department of Commerce
Patent and Trademark Office

Docket No.
TIBO-0029

Application No.
09/836,477

Applicant
Brendan Larder, Stuart Bloor, Kurt Hertogs, Pascale
Alfons Rosa Dehertogh and Rudy Jean Marc Mortier

Filing Date
April 18, 2001

Group
1631

Confirmation No.
8810

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

1	Beroud, et al., "UMD (Universal Mutation Database): A Generic Software to Build and Analyze Locus-Specific Databases," <i>Human Mutation</i> , 2000 , 15(1), 86-94
2	Cohen, C. et al. 3 Abstracts, "Phenotypic Resistance Testing Significantly Improves Response to Therapy: A Randomized Trial," "Exploration of HIV-Infection as a Risk Factor for Symptomatic Plasma Cell Endometritis," "Forty-Eight Week Analysis of Patients Receiving T-20 as a Component of Multi-Drug Salvage Therapy," <i>XIII International AIDS Conference</i> , 2000
3	D'Aquila, R.T., "HIV-1 Chemotherapy and Drug Resistance," <i>Clinical Diagnostic Virology</i> , 1995 , 3, 299-316
4	De Gruttola, V. et al., "The Relation between Baseline HIV Drug Resistance and Response to Antiretroviral Therapy; Re-Analysis of Retrospective and Prospective Studies Using a Standardized Data Analysis Plan," <i>Antiviral Therapy</i> , 2000 , 5, 41-48
5	De Leon, et al., "Clinical Features and Genotype-Phenotype Correlations in 41 Italian Families with Adenomatosis Coli," <i>Italian Journal of Gastroenterology and Hepatology</i> , 1999 , 31(1), 850-860
6	Eastman, P.S., "Comparison of Selective Polymerase Chain Reaction Primers and Differential Probe Hybridization of Polymerase Chain Reaction Products for Determination of Relative Amounts of Codon 215 Mutant and Wild-Type HIV-1 Populations," <i>Journal of Acquired Immune Deficiency Syndrome and Human Retrovirology</i> , 1995 , 9, 264-273
7	Edman, P., "Sequence Determination," <i>Mol. Biol. Biochem. Biophys</i> , 1970 , 8, 211-255
8	Estellar, M. et al., "Inactivation of the DNA-Repair Gene <i>MGMT</i> and the Clinical Response of Gliomas to Alkylating Agents," <i>New England Journal of Medicine</i> , 2000 , 343, 19, 1350-1354
9	Fodor, S.P. et al., "Multiplexed Biochemical Assays with Biological Chips," <i>Nature</i> , 1993 , 364, 555-556
10	Graber, J. et al., "Differential Sequencing with Mass Spectrometry," <i>Genetic Analysis: Biomolecular Engineering</i> , 1999 , 14, 215-219

EXAMINER

DATE CONSIDERED



Form PTO-1449 Modified List of Patent and Publications Cited by Applicant (Use several sheets if necessary) U.S. Department of Commerce Patent and Trademark Office		Docket No. TIBO-0029	Application No. 09/836,477
		Applicant Brendan Larder, Stuart Bloor, Kurt Hertogs, Pascale Alfons Rosa Dehertogh and Rudy Jean Marc Mortier	
		Filing Date April 18, 2001	Group 1631
		Confirmation No. 8810	
OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)			
	11	Hertogs, K. et al., "A Rapid Method for Simultaneous Detection of Phenotypic Resistance to Inhibitors of Protease and Reverse Transcriptase in Recombinant Human Immunodeficiency Virus Type 1 Isolates from Patients Treated with Antiretroviral Drugs," <i>Antimicrobial Agents Chemotherapy</i> , 1998 , 42(2), 269-276	
	12	Hirsh, et al., "Antiretroviral Drug Resistance Testing in Adult HIV-1 Infection," <i>The Journal of American Medical Association</i> , May 2000 , 283(18), 2417-2426	
	13	Japour, A.J. et al., "Standardized Peripheral Blood Mononuclear Cell Culture Assay for Determination of Drug Susceptibilities of Clinical Human Immunodeficiency Virus Type 1 Isolates", "The RV-43 Study Group & The ACTG Virology Committee Resistance Working Group," <i>Antimicrobial Agents Chemotherapy</i> , 1993 , 37, 1095-1101	
	14	Jeanpierre, et al., "Software and Database for the Analysis of Mutation in the Human WT1 Gene," <i>Nucleic Acids Research</i> , 1998 , 26(1), 271-274	
	15	Kellam, P. et al., "Recombinant Virus Assay: A Rapid, Phenotypic Assay for Assessment of Drug Susceptibility of Human Immunodeficiency Virus Type 1 Isolates," <i>Antimicrobial Agents and Chemotherapy</i> , 1994 , 38, 23-30	
	16	King, P.J. et al., "Resistance to the Anti-Human Immunodeficiency Virus Type 1 Compound L-Chicoric Acid Results from a Single Mutation at Amino Acid 140 of Integrase," <i>Journal of Virology</i> , 1998 , 72(10), 8420-8424	
	17	Larder, B.A. et al., "Zidovudine Resistance Predicted by Direct Detection of Mutations in DNA from HIV-Infected Lymphocytes," <i>Aids</i> , 1991 , 5, 137-144	
	18	Larder, et al., "A Complete Survey, In Over 1,500 Clinical HIV-1 Isolates, of Phenotypic and Genotypic Protease Inhibitor Resistance Profiles (Including Gag Cleavage Site Sequences) and Their Relation to Therapy History," <i>AIDS</i> , 1998 , 12(4), S11, OP3.5	
	19	Larder, B.A. et al., "Use of Neural Networks to Define the Genetic Basis of HIV-1 resistance to d4T," <i>Fifth International Conference on Drug Therapy in HIV Infection, Glasgow</i> , 2000 , 14(4), PL 9.5	
	20	Laurent-Puig Pierre, et al., "APC Gene: Database of Germline and Somatic Mutations in Human Tumors and Cell Lines," <i>Nucleic Acids Research</i> , 1998 , 26(1), 269-270	
EXAMINER		DATE CONSIDERED	



Form PTO-1449 Modified List of Patent and Publications Cited by Applicant (Use several sheets if necessary) U.S. Department of Commerce Patent and Trademark Office		Docket No. TIBO-0029	Application No. 09/836,477
		Applicant Brendan Larder, Stuart Bloor, Kurt Hertogs, Pascale Alfons Rosa Dehertogh and Rudy Jean Marc Mortier	
		Filing Date April 18, 2001	Group 1631
		Confirmation No. 8810	
OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)			
	21	Pauwels, R. et al., "Comprehensive HIV Drug Resistance Monitoring Using Rapid, High-Throughput Phenotypic and Genotypic Assays With Correlative Data Analysis," <i>2nd International Workshop on HIV Drug Resistance and Treatment Strategies, Lake Maggiore, Italy, June 24-27, 1998, Abstract 51, 35-36</i>	
	22	Pauwels, R. et al., "Correlation between Genotypic and Phenotypic Resistance Data in AVANTI," <i>Abstracts of the Interscience Conference on Antimicrobial Agents and Chemotherapy, 1997, 37, 263-264 I-112</i>	
	23	Peipkorn, M., "Genetic Basis of Susceptibility to Melanoma," <i>Journal of the American Academy of Dermatology, 1994, 31(6), 1022-1039 (Abstract only)</i>	
	24	Petropoulos, C.J. et al., "A Novel Phenotypic Drug Susceptibility Assay for Human Immunodeficiency Virus Type 1," <i>Antimicrobial Agents Chemotherapy, 2000, 44(4), 920-928</i>	
	25	Petropoulos, C.J. et al., "Human Immunodeficiency Virus 1, Complete Genome," <i>Database Genebank NCBI, 2000, Accession nr. NC_001802, 11 pages</i>	
	26	Reinke, et al., "Natural Selection Results in Conservation of HIV-1 Integrase Activity Despite Sequence Variability," <i>AIDS, 2001, 15(7), 823-830</i>	
	27	Robertson, K.D. et al., "DNA Methylation in Health and Disease," <i>Nature Reviews, 2000, 1, 11-19</i>	
	28	Sanger, F. et al., "DNA Sequencing with Chain Terminating Inhibitors," <i>Proc. Natl. Acad. Sci., 1977, 74, 5463-5467</i>	
	29	Schinazi, R.F. et al., "Mutations in Retroviral Genes Associated with Drug Resistance," <i>International Antiviral News, 1997, 5(8), 129-142</i>	
	30	Shafer, R., "Human Immunodeficiency Virus Reverse Transcriptase and Protease Sequence Database," <i>Nucleic Acids Research, 1999, 27(1), 348-352</i>	
	31	Skinner, et al., "Analysis of a Large Collection of Natural HIV-1 Integrase Sequences, Including those from Long-Term Nonprogressors," <i>Journal of Acquired Immune Deficiency Syndromes and Human Retrovirology, 1998, 19(2), 99-110</i>	
	32	Stuyver, L. et al., "Line Probe Assay for rapid Detection of Drug-Selected Mutations in the Human Immunodeficiency Virus Type 1 Reverse Transcriptase Gene," <i>Antimicrobial Agents and Chemotherapy, 1997, 41, 284-291</i>	
EXAMINER		DATE CONSIDERED	



Form PTO-1449 Modified List of Patent and Publications Cited by Applicant (Use several sheets if necessary) U.S. Department of Commerce Patent and Trademark Office		Docket No. TIBO-0029	Application No. 09/836,477
		Applicant Brendan Larder, Stuart Bloor, Kurt Hertogs, Pascale Alfons Rosa Dehertogh and Rudy Jean Marc Mortier	
		Filing Date April 18, 2001	Group 1631
		Confirmation No. 8810	
OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)			
	33	Vandamme, A-M. et al., "Laboratory Guidelines for the Practical Use of HIV Drug Resistance Tests in Patient Follow-Up," <i>Antiviral Therapy</i> , 2001 , <i>6(1)</i> , 21-39	
	34	Woerner, A.M. et al., "Characterization of a DNA Binding Domain in the C-Terminus of HIV-1 Integrase by Deletion Mutagenesis," <i>Nucleic Acids Research</i> , 1993 , <i>21(15)</i> , 3507-3511	
	35	Yates, J., "Mass Spectrometry from Genomics to Proteomics," <i>Trends in Genetics</i> , 2000 , <i>16</i> , 5-8	
EXAMINER		DATE CONSIDERED	

Form PTO-1449 Modified List of Patent and Publications Cited by Applicant (Use several sheets if necessary) U.S. Department of Commerce Patent and Trademark Office				Docket No. TIBO-0029		Application No. 09/836,477	
				Applicant Brendan Larder, Stuart Bloor, Kurt Hertogs, Pascale Alfons Rosa Dehertogh and Rudy Jean Marc Mortier			
				Filing Date April 18, 2001		Group 1631	
				Confirmation No. 8810			
U. S. PATENT DOCUMENTS							
Examiner Initial		Document No.	Date	Name	Class	Subclass	
	36	5,202,259	04/13/1993	Goff, et al.	435	252.33	
	37	6,087,093	07/11/2000	Lieven, et al.	435	5	
	38	6,221,578 B1	04/24/2001	de Bethune et al.	435	5	
	39	6,869,759	03/22/2005	Parkin et al.	435	5	
FOREIGN PATENT DOCUMENTS							
Examiner Initial		Document No.	Date	Country	Translation		
					YES	NO	
	40	EP 0 203 200 B1	01/24/1990	EPO			
	41	WO 94/16737	08/04/1994	PCT			
	42	WO 97/27480	07/31/1997	PCT			
	43	WO 99/40227	08/12/1999	PCT			
	44	WO 99/61658	12/02/1999	PCT			
EXAMINER				DATE CONSIDERED			



Form PTO-1449 Modified List of Patent and Publications Cited by Applicant (Use several sheets if necessary) U.S. Department of Commerce Patent and Trademark Office	Docket No. TIBO-0029	Application No. 09/836,477
	Applicant Brendan Larder, Stuart Bloor, Kurt Hertogs, Pascale Alfons Rosa Dehertogh and Rudy Jean Marc Mortier	
	Filing Date April 18, 2001	Group 1631
	Confirmation No. 8810	

U. S. PATENT DOCUMENTS

Examiner Initial		Document No.	Date	Name	Class	Subclass

FOREIGN PATENT DOCUMENTS

Examiner Initial		Document No.	Date	Country	Translation	
					YES	NO
	45	WO 99/67427	12/29/1999	PCT		
	46	WO 00/73511 A1	12/07/2000	PCT		
	47	WO 00/78996 A1	12/28/2000	PCT		
	48	WO 01/16860	03/08/2001	PCT		
	49	WO 01/57245 A2	08/09/2001	PCT		

EXAMINER	DATE CONSIDERED
-----------------	------------------------